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Effects of custom mold with peripheral textured surface foot orthosis on balance and physical function in subjects with chronic ankle instability

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Abstract

Introduction: Currently, healthcare professionals recommend an initial conservative approach consisting of non-pharmacological approaches for chronic ankle instability. We developed a foot orthosis targeting both mechanical and functional instability in these patients, aiming to investigate its effects on balance and physical function.
Methods: This research is a randomized controlled trial that included 45 young individuals who are active and have chronic ankle instability. The participants were recruited from sports clubs. The participants were separated into three groups: a control group without any intervention, a group prescribed with a custom mold foot orthosis, and a group prescribed with a custom mold with peripheral textured surface foot orthosis. Balance was assessed using single-leg balance and single-leg hop tests, while physical function was evaluated using the FAAM questionnaire. Data analysis was performed using one-way analysis of covariance statistical test.
Results: Both types of foot orthoses were found to enhance balance and physical function. The foot orthosis with peripheral textured surface exhibited superior results compared to custom mold foot orthosis, as it significantly increased the score of the single leg hop test (p=0.01) and the FAMM-sport section (p=0.002).
Discussion: The foot orthosis with peripheral textured surface can potentially optimize the subtalar joint alignment and modify the sensory input generated by the activation of mechanoreceptors located in the sole region of the foot. This alteration may further enhance balance and physical function.

Take-home message: Foot orthoses, designed to change the action of the sensorimotor mechanism in the human body, have demonstrated favorable outcomes in improving balance and physical function among chronic ankle instability subjects.
Key words: balance; chronic ankle instability; insole.

INTRODUCTION

Lateral ankle sprain (LAS) is a prevalent musculoskeletal damage that impacts both athletes and individuals engaged in physical activity [1]. This injury accounts for 33-73% of ankle injuries [2]. Approximately 23,000 sprains occur daily in the United States [3,4], although the actual statistics are higher because 56.8% of people who experience sprains do not seek medical treatment [3,5]. In 55 to 72 percent of patients, despite the rehabilitation process, chronic symptoms such as giving way and repeated LAS persist in the ankle joint [6,7]. Such Repetitive injuries can cause Chronic Ankle Instability (CAI). CAI is marked by mechanical, functional, or both types of instability [8]. In cases of mechanical instability, the joint capsule and ligaments become lax as a result of acute LAS. This laxity leads to increased subtalar joint lateral misalignment and a heightened risk of re-spraining due to greater inversion torque during rapid movements. Sensory disorder of the ankle and foot complex is the main cause of functional ankle instability. The function of the sensorimotor system relies on afferent signals from joints, tendons, ligaments, capsules, and skin mechanoreceptors [8-11]. During LAS, the mechanoreceptors in the lateral skin, ligament, and ankle capsule are compromised, as they have a low capacity for withstanding tensile forces [12]. Difficulties in ankle joint physical function among individuals with CAI can stem from deficits in peroneal and tibialis anterior muscle reactions [13], local sensory perception [12], proprioception, and balance [14-17].

The most common treatment approaches derived from rehabilitation programs place significant focus on improving balance [18] and physical function [19]. Orthotic devices are frequently utilized in the rehabilitation process for these patients. Ankle and Foot Orthoses (AOs and FOs) have been proposed as potential solutions to address balance deficits in this population [18,20]. While AOs have shown efficacy in preventing LAS [21], the restriction of ankle motion caused by these orthoses may lead to adverse effects on the knee due to alterations in the closed kinematic chain of the lower limb [22].

The satisfaction rate reported by patients using FOs was 70-80% [23]. FOs show different effects according to their design and purpose. They have been employed to regulate heel-to-toe movements [24-26], diminish biomechanical stress [27], provide arch support [28], and position the subtalar joint in a neutral alignment [24,28] in repetitive LAS. In three studies, FOs were used to improve the sensory input with textured surfaces [28-30]. There is a high concentration of mechanoreceptors in the plantar region of the feet [31]. The significance of plantar foot mechanoreceptors becomes more prominent in CAI when there is a lack of valuable sensory information received from the mechanoreceptors located on the lateral structure of the ankle [32].

In research studies, custom-molded and textured FOs have received more attention [33]. Custom-molded FOs primarily aim to restore foot alignment, whereas textured FOs have been studied for their impact on sensory input [33]. It is important to note that patients with CAI may experience different instabilities [8], which may not be effectively addressed using the same type of FOs. One potential approach to enhance the therapeutic impact of orthotic treatment for CAI is to integrate a textured surface into custom-molded FO [28]. This modification can potentially augment the orthosis's positive effects, catering specifically to the mechanical and functional instabilities of CAI patients.

Maki et al. suggested a unique form of textured surface characterized by a raised ridge positioned around the perimeter instead of an array of indentations typically used to stimulate mechanoreceptors on the foot sole. The authors proposed that this design aids the central nervous system in perceiving the borders of the base of support. As the center of mass approaches the edges of the base of support, a slight concavity forms along the foot's skin, resulting in stimulation of mechanoreceptors in the sides of the foot and subsequent changes in afferent sensory input transmission [34]. Subsequent research has further investigated the implementation of prefabricated FOs equipped with a peripheral textured surface to improve balance [35-37]. In this study, we made a modification to a custom-molded FO by incorporating a peripheral raised ridge. The effects of using the custom mold with a peripheral textured surface FO (CPTFO) on balance and physical function were assessed for a duration of 4 weeks. These effects were then compared to a group using custom mold FO (CFO) and a control group without any intervention.

METHODS

Study setting

This randomized controlled trial took place between March 2022 and May 2023. The study protocol received approval from the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences, with the assigned code IR.USWR.REC.1400.301. Participants were given a consent form to read and sign before participation. Data collection procedures were carried out at the Orthotics and Prosthetics Department of the University of Social Welfare and Rehabilitation Sciences. Participants in the intervention groups were instructed to use FOs for a duration of 4-8 hours daily over a period of 4 weeks. One of the researchers conducted weekly phone calls to assess and monitor the amount and manner of FO usage. Each participant underwent assessment twice, once before starting the intervention and again after 4 weeks of FO usage.

Study population

A total of 45 patients were recruited from sports clubs in Tehran province, Iran. To be eligible, patients with CAI needed to meet specific criteria outlined by the statement released by the International Ankle Consortium [38]. These factors included: (1) Patients must have a documented history of at least one significant LAS occurring 12 months or more prior to the study, resulting in inflammatory symptoms like pain and swelling that caused a disruption in desired physical activities

lasting for at least one day; (2) Patients should self-report ankle joint instability and have experienced multiple recurrent ankle sprains (at least two episodes) within the six months leading up to the study.

Subjective feelings of instability were further confirmed using the Cumberland Ankle Instability Tool (CAIT), a validated questionnaire with a score below 24 indicates the presence of CAI (Persian version); (3) Participants were required to score below 90% in the daily activities section and below 80% in the sports activities section of the Persian version of the Foot and Ankle Ability Measure (FAAM) questionnaire. The study also had specific exclusion criteria, including: (1) Prior lower extremity operation bone fracture (2) Balance problems caused by underlying diseases such as diabetes and cavus deformity.

Randomization

Participants were randomly categorized into one of three groups: CPTFO, CFO, or a control group with no intervention. The randomization was performed in an equal distribution of 1:1:1 using a block randomization method with a block volume of 6.

Blinding

The study employed a concealed allocation procedure, ensuring that the examiner remained unaware of the allocation. This was accomplished by utilizing sealed opaque envelopes. Randomization responsibilities were assigned to an individual separate from the examiner and therapists involved in the study. Furthermore, statistical analyses were performed by an independent biostatistician who was not responsible for conducting the examinations, interventions, or randomization.

Interventions

To fabricate both orthoses, negative casts of the foot were constructed using plaster bandage while the patient was seated on a chair, ensuring that the subtalar joint remained in a neutral position, the midtarsal joint in maximum pronation, and the first ray in a neutral alignment [39] (p. 202). All negative casts were obtained by an orthotics and prosthetics specialist. Polypropylene sheets with a thickness of 5 mm were heated to 140 degrees and stretched onto modified positive molds. This process resulted in the creation of CFO (Figure 1A). The CFO primarily consisted of a medial longitudinal arch support and a 2 cm heel cup. The orthosis trim was expanded on both sides below the medial and lateral malleolus. The length of the orthosis was extended to reach the metatarsal heads. To produce CPTFO, a layer of soft foam (shore 30) with a thickness of 1 mm was initially affixed to the upper surface of the CFO. Subsequently, a 3 mm diameter strip of ethylene vinyl acetate foam (Shore A50) was attached along the edge of the CFO, maintaining a distance of 1 centimeter from the edges (Figure 1B).

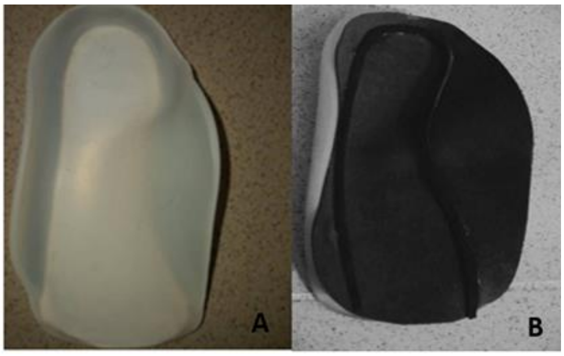

Figure 1. (A) Custom mold FO; (B) Custom mold with a peripheral textured surface FO.

Study outcomes

The study evaluated four outcomes: dynamic balance, static balance, Activity of Daily Living (ADL), and sports activity. Dynamic balance was assessed using the Single Leg Hop Test (SLHT), which required participants to jump as far as possible using their affected side while landing in a controlled and stable manner. There were no restrictions on body or arm movements during the test. The distance between the starting point and the endpoint, as indicated by the placement of the heel, is measured and recorded in centimeters.

The Single Leg Stance Test (SLST) was used to assess static balance. Participants stood on their affected leg while placing their hands on the iliac crest, with the unaffected knee flexing but not touching the weight-bearing limb. The objective was to sustain this posture for a duration of 30 seconds while keeping their eyes closed. The investigator recorded various parameters, including instances of the sound leg or weight-bearing leg touching the floor, foot displacements from the starting position, hand separations from the iliac crest, and eye openings. The number of errors was recorded for subsequent analysis.

Previous studies have confirmed the efficacy of SLHT and SLST in identifying balance impairments related to musculoskeletal injuries such as CAI [40,41]. Prior to conducting these tests, participants received instructions to ensure accurate

performance. They performed the tests three times for familiarization and learning purposes, and then the average of the three main test results was used for analysis.

Physical function was evaluated using FAAM questionnaire, which assessed physical function across two levels: ADL and sports activity. The ADL section consisted of 21 questions, while the sports activity section comprised 8 questions. Scores on the questionnaire ranged from 0 to 84 for the ADL section and from 0 to 32 for the sports activity section. The reliability and validity of the Persian version of FAAM for assessing functional limitations in individuals with foot and ankle abnormalities have been documented [42].

Statistical analysis

G power software (version 3.1) was used to calculate the sample size (power: 80%, confidence level: 95%, and effect size: 0.45) [39]. The final sample size comprised 45 participants, with 15 individuals allocated to each of the 3 groups.

We used SPSS software (version 26) for statistical analysis. One-way analysis of variance was used to detect differences in demographic characteristics. Within and between group changes were analyzed with paired t-tests and analysis of covariances tests, respectively. Cohen d effect was run to show the interventions effectiveness.

RESULTS

Out of the 45 participants initially assigned to the three groups, 43 individuals successfully finished the study. The flow diagram, following the CONSORT statement guidelines, is depicted in Figure 2.

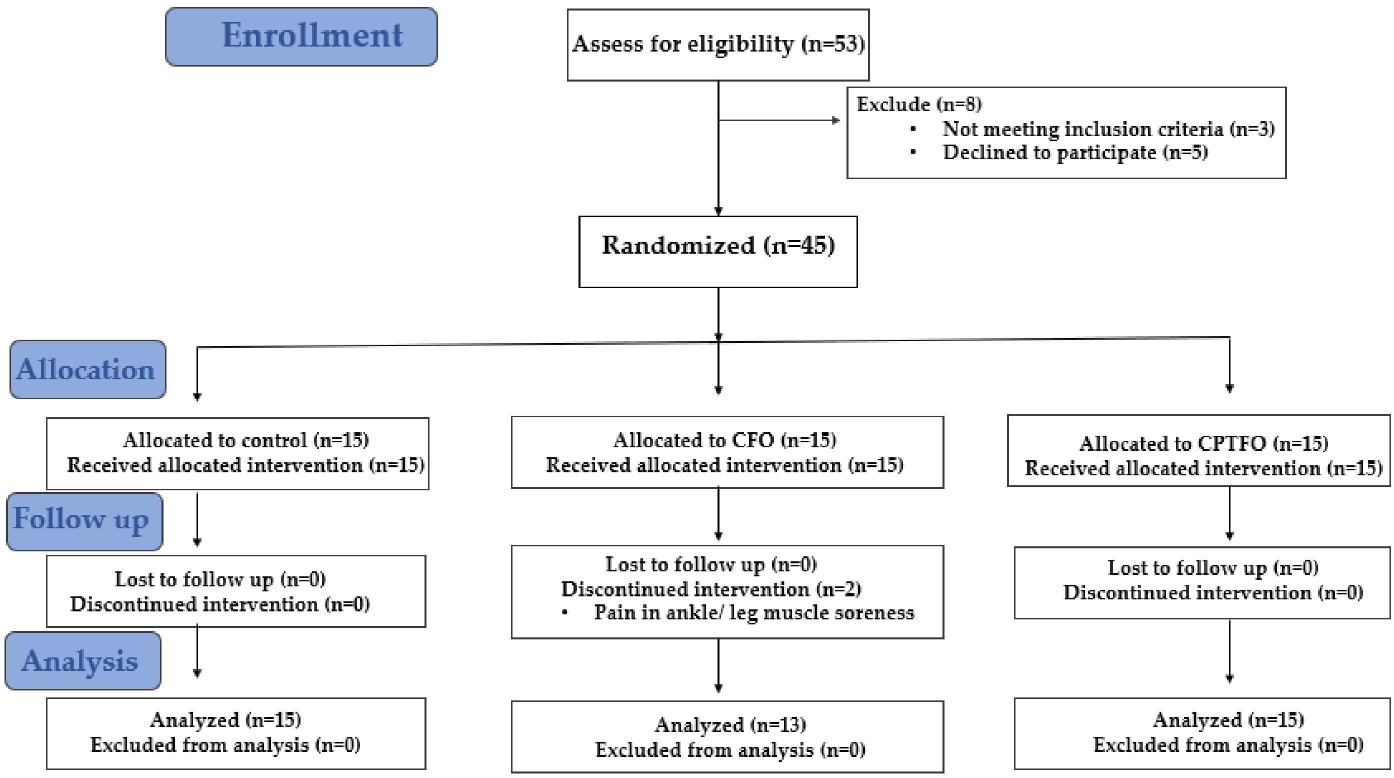

Figure 2. Consort Statement follow diagram.

Table 1 presents a summary of the demographic data for the participants. At the study's beginning, significant weight and age disparities were observed among the three participant groups. Recognizing these variables as potential confounding factors, adjustments were made during the ANCOVA analysis to minimize their influence on the results.

Table 1. Mean ± SD values of demographic variables and the result of one-way analysis of variance for these variables.

	Control	**CFO**	**CPTFO**	**P value**
Age	25.73±3.9	26.40±7	23.91±4.9	**0.01**
Weight	65.8±11.3	63.8±11.6	67.1±8.9	**0.04**
Height	161.8±4.7	163.07±7.5	164.1±8.3	0.32
CAIT score	14.8±3.1	15.2±1.4	15.8±3.2	0.16
FAAM- sport (%)	67.5±9.99	65.5±10.4	76.11±14	0.98
FAAM-ADL (%)	79.5±7.8	80.3± 5.9	67.8±13.9	0.05
Time since last LAS	20.8±5.14	21.9±4.47	24.3±4.2	0.17

Note: CAIT, Cumberland Ankle Instability Tool; FAAM, Foot and Ankle ability measure; ADL, activity of daily living;

Within-group comparisons demonstrated significant improvements FAAM-ADL, FAAM-sport, SLST, and SLHT for two intervention groups, while no significant results were observed for the control group (Table 2).

Table 2. Paired t-test and effect size for outcomes.

	Group 1: control	**P value**	**Cohen d**	**Group 2: CFO**	**P value**	**Cohen d**	**Group 3: CPTFO**	**P value**	**Cohen d**
FAAM ADL (%)									
pre	79.5±7.8	0.9	0.08	80.3± 5.9	**0.02**	**0.45**	67.8±13.9	**0.01**	**0.33**
post	80.1±6.8			84±5.6			71.6±11.3		
FAAM sport (%)									
pre	67.5±9.99	0.6	0.13	65.5±10.4	**0.01**	**0.84**	76.11±14	**0.001**	**0.9**
post	68.8±8.7			70.68±9.9			86.5±5.53		
SLST									
pre	7.21±4.75	0.65	0.07	8.54±5.9	**0.001**	**1.89**	8.42±5.4	**0.001**	**2.18**
post	7.29±4.5			3.13±4.1			2.96±2.1		
SLHT									
pre	104.2±31.8	0.76	0.05	68.7±20.3	**0.009**	**0.89**	88.9±20.1	**0.001**	**1.95**
post	104.36±31.7			84.9±24.5			110.8±18.2		

Note: SLST, single leg stance test; SLHT, single leg hop test

Effect levels of 0.2, 0.5, and 0.8 are widely acknowledged as small, moderate, and large, respectively. This study's findings revealed moderate to large effect sizes (d = 0.33-2.18), indicating support for the clinical effectiveness of both interventions.

Table 3. Mean values ±SD of differences of outcomes and the analysis of covariance results.

	Group 1: control	Group 2: CFO	Group 3: CPTFO	Results of co-variate analysis	Significant results in Bonferroni comparison
FAAM ADL (%)	0.6±2.6	3.7±1.4	3.8±3.2	0.01	**1<2, 1 <3**
FAAM sport (%)	1.3±2.3	5.18±2.5	10.39±2.6	0.003	**1 <2, 1<3, 2 <3**

SLST	0.08±1.2	-5.41±1.3	-5.46±1.05	0.01	**2<1, 3<1**
SLHT	0.16±8.1	16.2±5.8	21.9±4.9	0.001	**1 <2, 1<3, 2 <3**

The analysis of covariance results revealed significant differences between the groups for all four outcome measures, as shown in Table 3. Post hoc analysis revealed that both the CFO (p=0.001) and CPTFO (p=0.001) groups exhibited significantly higher scores in FAMM ADL compared to the control group. However, the CPTFO group exhibited higher FAAM sports scores compared to the CFO group (p=0.002) and the control group (p=0.001).

Regarding the number of errors in SLST, the control group had a significantly higher count compared to both the CFO group (p=0.001) and the CPTFO group (p=0.001). Additionally, the SLHT distance in centimeters was higher in the CPTFO group relative to both the CFO group (p=0.01) and the control group (p=0.001).

DISCUSSION

The findings of this study suggest that both types of FOs significantly impact static and dynamic balance, as measured by SLBT and SLHT, respectively. Moreover, the results indicate that CPTFO has a greater effect on the FAAM sport section and SLHT.

The primary outcome of this study revealed an improvement in balance and physical function through the use of CFO and CPTFO. These results are consistent with prior studies emphasizing the efficacy of FOs in improving balance in individuals with CAI [18]. It is proposed that FOs elicit both mechanical and functional impacts on the foot and ankle motions in CAI [28,29].

Two studies have reported that CFOs incorporating a heel cup and medial longitudinal arch support have the ability to significantly enhance the reaching distance in the SEBT [28,43]. The SEBT is considered a reliable assessment tool for detecting balance impairments in individuals with CAI [44]. LAS can result in excessive motion of the subtalar joint and lead to tilting of the talus while standing in the talocrural joint [8]. CFOs have been found to influence balance maintenance through several mechanisms, including reducing the subtalar joint range of motion [28,45], promoting proper alignment of the foot [46], and alleviating stress on the foot and ankle complex muscles [25].

The second outcome of this study demonstrated that CPTFO expressed superior improvements in SLHT performance and the score of the FAAM sport section for patients with CAI, when compared to both the CFO and control groups.

Previous studies have demonstrated the beneficial impact of textured FOs on balance improvement [28,29]. The improvement of FAAM sports scores can be seen as the reason that dynamic balance is the basis of physical function [47]. The primary reason for the effect of textured FOs is the alteration in the quantity and spatiotemporal patterns of sensory feedback from the foot sole [48].

The third finding of this study indicated that CPTFO did not have a significantly higher impact on SLST and FAAM-ADL compared to CFO. It has been suggested that static tests may not provide sufficient challenge to effectively assess the sensorimotor system [40]. The enhanced stability provided by CPTFO is particularly noticeable during activities that involve a greater challenge to balance, such as sports activities [49]. The primary motions of the ankle joint, namely plantarflexion, and dorsiflexion, occur within the sagittal plane. The range of motion within this plane typically spans from 65 to 75 degrees, incorporating 10 to 20 degrees of dorsiflexion and 40 to 55 degrees of plantar flexion [50]. In ADLs like gait, around 10 to 20 degrees of dorsiflexion are necessary, while sports activities like running require up to 30 degrees, and squats require approximately 40 degrees [51]. In sports activities, various body parts deviate further from their anatomical position, necessitating greater coordination to maintain balance. This observation emphasizes the role of the peripheral raised ridge in improving afferent information from mechanoreceptors.

It is crucial to acknowledge that this study also encountered certain limitations. It is essential to note that this study was conducted exclusively on a sample of active young individuals with CAI. Therefore, caution should be taken to not generalize the results to the broader population or patients who frequently experience sprains due to underlying conditions such as Cavus deformity. Furthermore, this study focused on examining the short-term effect of using insoles over a one-month period. To explore the long-term impact, further studies should be designed and conducted. Finally, the strength of the peroneal muscles, which play a crucial role as the primary lateral stabilizers of the ankle, was not measured. This decision was based on the assumption that individuals involved in sports activities typically exhibit a muscle grade ranging from 4 to 5. For future study designs, it is recommended to address the aforementioned limitations. Additionally, it is suggested that the designed FOs be compared with other types of FOs specifically intended to impact the sensorimotor system of the human body, as well as commonly used orthoses for the target population.

CONCLUSIONS

Both the CFO and the CPTFO have demonstrated the ability to enhance static and dynamic performance in patients with CAI. However, it is worth noting that the CPTFO appears to be the preferred choice among these two FOs for prescribing to these patients. This particular FO exhibits a greater impact on improving SLHT performance and the FAMM sports section.

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